

EXHIBIT 16

2019 WL 7753453

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United States District Court, S.D. Florida.

Charlotte SALINERO, et al., Plaintiffs,

v.

JOHNSON & JOHNSON, et al., Defendants.

Case No. 1:18-cv-23643-UU

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Signed 09/05/2019

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ORDER

URSULA UNGARO, UNITED STATES DISTRICT JUDGE

*1 THIS CAUSE is before the Court upon Defendants Johnson & Johnson (“J&J”) and Ethicon, Inc.’s (“Ethicon”) (collectively, the “Defendants”) *Daubert* Motion to Exclude Testimony of Plaintiffs’ Expert Witnesses (the “Motion”). D.E. 156. The Court has reviewed the pertinent portions of the record and is otherwise fully advised in the premises. For the reasons set out below, the Motion is GRANTED IN PART AND DENIED IN PART.

I. BACKGROUND

Defendant Ethicon designs and manufactures Artisyn Mesh, a product used as a bridging material with abdominal sacrocolpopexy where surgical treatment for uterovaginal

prolapse is warranted. *See* D.E. 134 at 7 ¶ 5(f)–(h). Artisyn Mesh contains polypropylene. D.E. 20 ¶ 29; D.E. 26 ¶ 29; D.E. 27 ¶ 29. In December of 2012, Plaintiff Charlotte Salinero (“Mrs. Salinero”) was treated for her Stage IV pelvic organ prolapse by abdominal sacrocolpopexy with Artisyn Mesh. *See* D.E. 134 at 7 ¶ 5(b)–(c). In 2017, Mrs. Salinero endured a lengthy revision surgery to treat a fistula and other complications allegedly due to erosion and migration of the Artisyn Mesh into Mrs. Salinero’s bladder, rectum, and vagina. *See id.* at 1–2 ¶ 1(a), 5 ¶ 1(b), 7 ¶ 5(d)–(e); *see also* D.E. 20 ¶¶ 36, 57; D.E. 134 at 1–2, 5.

Mrs. Salinero alleges significant injuries due to design and manufacturing defects in and inadequate warnings concerning the risks associated with Artisyn Mesh. At trial, Plaintiffs intend to offer the testimony of their retained expert witnesses: Dr. Michael Margolis (“Dr. Margolis”); Dr. Vladimir Iakovlev (“Dr. Iakovlev”); Dr. Scott Guelcher (“Dr. Guelcher”); and Dr. Russell Dunn (“Dr. Dunn”). *See* D.E. 134. On May 31, 2019, Defendants moved to exclude the testimony of all four of these proposed witnesses. D.E. 156. The Motion is fully briefed and ripe for disposition.

II. LEGAL STANDARD

Federal Rule of Evidence 702 states: “A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.”

The Supreme Court set forth the criteria for the admissibility of scientific expert testimony under Rule 702 in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), by instructing trial judges to “determine at the outset, pursuant to Rule 104(a),¹ whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue,” which includes “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and or whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592–93. In *Kumho Tire*, the Supreme Court subsequently held this standard to be applicable to all expert testimony,

holding that “*Daubert*’s general holding—setting forth the trial judge’s general ‘gatekeeping’ obligation—applies not only to testimony based on ‘scientific’ knowledge, but also to testimony based on ‘technical’ and ‘other specialized’ knowledge.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999).

*2 In *Rink v. Cheminova, Inc.*, the U.S. Court of Appeals for the Eleventh Circuit established a three-part test to determine whether expert testimony should be admitted under *Daubert*, explaining that all of the following elements must be established prior to the presentation of expert testimony to the jury:

- (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

400 F.3d 1286, 1291-92 (11th Cir. 2005). The party seeking to introduce expert testimony bears the burden of satisfying these criteria by a preponderance of the evidence. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999).

With respect to the qualification of an expert, the Eleventh Circuit has recognized that “[w]hile scientific training or education may provide possible means to qualify, experience in a field may offer another path to expert status.” *United States v. Frazier*, 387 F.3d 1244, 1261 (11th Cir. 2004). To determine whether a witness is qualified to testify as an expert regarding the matters he intends to address, this Circuit has held that a witness who possesses general knowledge of a subject may qualify as an expert despite lacking specialized training or experience, so long as his testimony would likely assist a trier of fact. See, e.g., *Maiz v. Virani*, 253 F.3d 641, 665 (11th Cir. 2001).

Even if a witness is qualified as an expert regarding a particular issue, the process used by the witness in forming

his expert opinion must be sufficiently reliable under *Daubert* and its progeny. See *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1342 (11th Cir. 2003) (stating that “one may be considered an expert but still offer unreliable testimony”). The Court of Appeals in *Frazier* quoted the advisory committee’s note to the 2000 amendments of Rule 702, which explains that “[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court’s gatekeeping function requires more than simply ‘taking the expert’s word for it.’ ” *Frazier*, 387 F.3d at 1261 (quoting Fed. R. Evid. 702 advisory committee’s note to 2000 amendments). Thus, the *Frazier* court observed, “it remains a basic foundation for admissibility that “[p]roposed [expert] testimony must be supported by appropriate validation—i.e., ‘good grounds,’ based on what is known.” *Id.* (quoting *Daubert*, 509 U.S. at 590).

The final requirement for admissibility of expert testimony is that it “assist the trier of fact.” *Frazier*, 387 F.3d at 1244. In other words, “expert testimony is admissible if it concerns matters that are beyond the understanding of the average lay person.” *Id.* (citing *United States v. Reno*, 765 F.2d 983, 995 (11th Cir. 1985)). Expert testimony “is properly excluded when it is not needed to clarify facts and issues of common understanding which jurors are able to comprehend for themselves.” *Hibiscus Assocs. Ltd. v. Bd. of Trs. of Policemen & Firemen Ret. Sys.*, 50 F.3d 908, 917 (11th Cir. 1995) (citations omitted).

*3 Notably, “[a] review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.” Fed. R. Evid. 702 advisory committee’s note to 2000 amendments. Although “[t]he judge’s role is to keep unreliable and irrelevant information from the jury because of its inability to assist in factual determinations, its potential to create confusion, and its lack of probative value,” this role “is not intended to supplant the adversary system or the role of the jury.” *Allison*, 184 F.3d at 1311–12. “[V]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Id.* at 1311 (citation omitted).

III. DISCUSSION

A. Dr. Margolis

Dr. Margolis is Plaintiffs' sole proffered clinician-expert. Plaintiffs propose that Dr. Margolis opine regarding the body's response to polypropylene-containing pelvic mesh and complications therefrom, as well as to the adequacy of Ethicon's warnings, testing and marketing efforts. *See* D.E. 156-2 ("Margolis Rep."). Defendants move to exclude both Dr. Margolis's general opinions about Artisyn Mesh and his case-specific causation opinions about Mrs. Salinero's alleged injuries.

As to the general opinions, Defendants argue: (1) much of Dr. Margolis's expert report in this case is copy-and-pasted from reports on Defendants' transvaginal mesh products (Prolift and TVT), even though (as he concedes) Artisyn Mesh is placed abdominally, not transvaginally; (2) Dr. Margolis has no experience at all with the Artisyn Mesh product, rendering him unqualified to offer any opinions on it; (3) Dr. Margolis's methodology is unreliable to the extent he relies on transvaginal mesh products and is conclusory, speculative and unsupported by evidence to the extent he purports to rely on two Artisyn-Mesh-related documents; (4) Dr. Margolis is unqualified to opine as to the adequacy of Defendants' warnings because he has no experience preparing product warnings and is unfamiliar with federal regulations governing product instructions for use ("IFU"); and (5) Dr. Margolis lacks any information relating to Ethicon's Artisyn Mesh testing and therefore cannot opine on the same.²

As to the case-specific opinions, Defendants argue: (1) Dr. Margolis fails to reliably link any particular defect in Artisyn Mesh to Mrs. Salinero's claimed injuries; and (2) Dr. Margolis's opinions about Mrs. Salinero's future prognosis are speculative.

1. Qualifications

a. Dr. Margolis is qualified to opine about the body's response to polypropylene products

Plaintiffs proffer ample evidence that "Dr. Margolis is a highly qualified urogynecologist, fellowship-trained and board certified female pelvic surgeon." D.E. 192 at 19; *see also id.* at 20–21 and supporting exhibits. Based on this evidence, as well as the opinion of Judge Goodwin of

the Southern District of West Virginia (the "MDL Court"), this Court agrees that Dr. Margolis is qualified to testify about the body's reaction to and the effect on polypropylene pelvic mesh and the complications caused by these mesh products. *See, e.g., In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-02327, 2016 WL 4536885, at *3 (S.D. W. Va. Aug. 30, 2016) (concluding that Dr. Margolis's "extensive clinical experience, combined with his review of and contributions to the medical literature, qualifies [him] to opine on mesh reaction to and effect on the human body" despite that he is not a biomaterials expert and has never performed "bench research" on polypropylene).

*4 Moreover, though Dr. Margolis has no experience with the Artisyn Mesh product specifically, he has extensive experience (both clinically and through research) with polypropylene-containing pelvic mesh generally. Such general knowledge satisfies the qualification element, even without specific knowledge of the narrowly-circumscribed subject of the case.³ *See Kaufman v. Pfizer Pharms.*, No. 1:02-cv-22692, at *2 (S.D. Fla. Aug. 4, 2011) ("[A] witness who possesses general knowledge of a subject may qualify as an expert despite lacking specialized training or experience, so long as his testimony would likely assist the trier of fact."). The qualification "inquiry is not stringent, and so long as the expert is minimally qualified, objections to the level of the expert's expertise go to credibility and weight, not admissibility." *Clena Invs., Inc. v. XL Specialty Ins. Co.*, 280 F.R.D. 653, 651 (S.D. Fla. 2012) (internal quotations and alterations omitted).⁴ Defendants are free to cross-examine Dr. Margolis about his lack of first-hand experience with the Artisyn Mesh product.

b. Dr. Margolis is not qualified to opine about IFU warnings, doctors' reliance on warnings and/or marketing, the Defendants' testing of Artisyn Mesh, or other marketing-related issues

The Court agrees with Defendants that Dr. Margolis is not qualified to opine that the IFU warnings are inadequate, that Ethicon failed to test Artisyn Mesh, and that Ethicon's marketing-related representations have been inadequate or misleading. *See generally* Margolis Rep. at 12–15, 18–42. Dr. Margolis lacks any education, training, or experience in marketing, product testing, or the drafting of IFU warnings. The Court is unpersuaded by Plaintiffs' conclusory argument that "qualified pelvic surgeons, as Dr. Margolis, who treat pelvic organ prolapse and the complications from

polypropylene mesh products, are certainly well-qualified to evaluate the adequacy of the warnings provided to physicians and surgeons who are considering the risks and benefits of a device or procedure before recommending it to their patients.” D.E. 192 at 22. The law requires more than Dr. Margolis’s *ipse dixit*. The MDL Court has excluded his opinions on these subjects accordingly. *See, e.g., In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, at *2–3 (S.D. W. Va. Aug. 30, 2016) (excluding testimony about what an IFU should or should not include and testimony regarding marketing strategy or techniques); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-02327, 2014 WL 186872, at *16 (S.D. W. Va. Jan. 15, 2014) (noting that “marketing is not Dr. Margolis’s field of expertise” and excluding marketing-related opinions). The Motion therefore is due to be GRANTED on this ground.⁵

2. Reliability

a. Copy-pasted material from reports on different polypropylene mesh products

*5 First, Defendants complain that Dr. Margolis’s report is largely copy-pasted from reports on transvaginal mesh products, whereas Artisyn Mesh is placed abdominally. Plaintiffs point to Dr. Margolis’s deposition testimony stating that the difference in implantation technique (abdominal versus transvaginal) is irrelevant to the “problematic portion of those mesh systems. ... Polypropylene is the issue. ... [I]t’s a different shape. It’s designed for a different implantation technique. But it’s the same mesh if you look at it microscopically.” D.E. 192 at 19 (emphasis in original) (quoting D.E. 165-1 (“Margolis Dep.”) at 67:10–21, 70:16–23).

Dr. Margolis’s opinions all stem from his personal experience explanting polypropylene meshes, his research, and his review of studies and other literature showing that any polypropylene mesh is likely to cause a negative foreign body response that can lead to further complications. Thus, the fact that Dr. Margolis will testify about his review of transvaginally-implanted mesh products containing polypropylene does not mean that the testimony is unreliable with respect to abdominally-implanted Artisyn Mesh containing polypropylene. Because Dr. Margolis’s opinions regarding the foreign body reaction to and the complications resulting from polypropylene in implanted

mesh are the same regardless of the implantation method, his inclusion of opinions from prior reports on Prolift and TVT are not necessarily unreliable under *Daubert*. Of course, Defendants may cross-examine Dr. Margolis on the distinctions they perceive between abdominally-implanted and transvaginally-implanted mesh.

So too with the fact that Prolift is made of non-absorbable material, Gynemesh PS, while Artisyn Mesh is made of partially-absorbable mesh, Gynemesh M (also known as Monocryl⁶). *See* Mot. at 2. According to his deposition testimony, Dr. Margolis’s opinion that the body’s reaction to and complications from polypropylene is “problematic” remains the same “whether they have Monocryl woven in with them or not, whether they are weaved into a certain pattern or not, whether they are made into a Y or not.” Margolis Dep. at 67:16–20; *see also id.* at 49:21–50:13; 127:1–3 (“my opinions about Artisyn mesh are similar to my opinions about all polypropylene systems”); 129:4–8 (“[I]t’s the same exact pathophysiology. Pathophysiology doesn’t change. Biology doesn’t change. The mesh changes name. But the biology, Mother Nature stays remarkably the same regardless of what you call it.”).

b. Reliance on small-pore heavyweight mesh despite Artisyn Mesh’s distinguishable pore size and weight

While the Court accepts that Dr. Margolis may testify reliably regarding the risks associated with presence of polypropylene in any mesh used to treat vaginal vault prolapse, including Artisyn Mesh, the Court cannot accept that Dr. Margolis’s opinion that Artisyn Mesh has an inadequate pore size, a lack of stability under load, and a lack of sufficient porosity (all of which lead to fibrotic bridging and scar plate formation) is reliable. *See* Margolis Rep. at 9. In his Expert Report, Dr. Margolis opines:

Small pore mesh has been demonstrated to increase fibrotic bridging which in turn leads to increased scar plate formation, contracture, shrinkage and effectively a stiffer mesh. The fibrotic bridging and scar plate prevents tissue in-growth and causes complications[.] ... In fact, Ethicon developed lighter weight, large pore meshes in order to

minimize the complications seen with heavyweight meshes like the Prolene used in TVT. These same biologic principles hold true for Artisyn mesh.

*6 *Id.* (footnote omitted). This opinion necessarily relies on the factual assumption that Artisyn Mesh has small pores, making it relatively heavy. However, in his deposition, Dr. Margolis conceded that the Artisyn Mesh has larger pores and is more lightweight than the Prolene used in TVT. Margolis Dep. at 67:22–71:6, 102:14–103:4. The thrust of Dr. Margolis’s opinion is that any polypropylene mesh is ultimately unsafe for implantation to address pelvic organ prolapse, but “if one was trapped on a desert island and had to put mesh in somebody” he would recommend larger pore, lightweight mesh because it has lower doses of the allegedly unsafe mesh. *See id.* And he admits that the pore size and weight of Artisyn Mesh more closely resembles the “safer” alternative of Ultrapro mesh. *See id.* Thus, his opinion that Artisyn Mesh is defective because its pore size is “small” and “heavy”—like TVT and Prolift—rests on a faulty premise and will be excluded because it is unreliable.

3. Case-Specific Opinions

a. Whether Mrs. Salinero’s injuries were caused by Artisyn Mesh’s small pore size and heavy weight

Dr. Margolis opines that Mrs. Salinero “suffered from the use of small pore, heavyweight mesh used in the Artisyn mesh product” and that “[i]n addition, the use of a lighter weight, larger pore mesh, less stiff, less rigid material similarly would have eliminated these risks caused by dense, small pore, stiff, non-porous mesh....” Margolis Rep. at 17. While Dr. Margolis’s general causation opinion that the implantation of synthetic polypropylene mesh is dangerous (as compared to, for example, native tissue repair) is based on a reliable methodology, his case-specific opinion that a larger pore mesh and/or lighter weight product should have been used in Mrs. Salinero’s case is not reliable.

b. Link between Mrs. Salinero’s implanted mesh and a specific defect

Next, Defendants argue that Dr. Margolis’s case-specific opinions that the design characteristics of Artisyn Mesh (for example, a propensity to contract, shrink, retract, to cause scarring, to erode and degrade) can cause serious complications are not specific enough to link Mrs. Salinero’s injuries to an alleged defect in the implant. Plaintiffs respond that Dr. Margolis sufficiently linked Mrs. Salinero’s injuries to her mesh implant. D.E. 192 at 23–24; *see also*, e.g., Margolis Rep. at 47 (concluding that Mrs. Salinero’s complications “are the direct result of the defects of the mesh including” the mesh’s propensity to, *inter alia*, degrade, erode, and cause fistula). At this gatekeeping stage, the Court agrees with Plaintiffs. It is clear that Dr. Margolis opines that the presence of polypropylene in vaginal mesh is itself a defect because of its propensity to erode and degrade.⁷ *See*, e.g., Margolis Rep. at 8–9, 11–12, 15–16. Dr. Margolis also reviewed Mrs. Salinero’s medical history, *see id.* at 44–47, and noted that evidence of degradation and erosion was present, *id.* at 45–47.⁸ This appears to sufficiently support the logical conclusion that the polypropylene in the Artisyn Mesh eroded into Mrs. Salinero’s bladder and caused the fistula and other complications. In other words, Dr. Margolis’s case-specific opinions appear to grounded on his general opinions and his review of Mrs. Salinero’s medical history and appear to be reliable, even if Dr. Margolis did not (and according to Plaintiffs, could not) examine the actual Artisyn Mesh explanted from Mrs. Salinero’s body.

*7 While the Court makes this preliminary ruling on Dr. Margolis’s case-specific defect opinions, the Court notes that each opinion at trial must be reliably linked to the specific alleged defect (other than the alleged small pores and heavy weight, which the Court has already found unreliable). The Court will rule on the admissibility of each opinion offered at trial as it arises.

c. Mrs. Salinero’s future prognosis

Finally, the Court agrees with Defendants that Dr. Margolis’s opinion about Mrs. Salinero’s future prognosis is mere speculation based solely on *ipse dixit*. It is one thing to form an opinion about a defect and causation based on a review of Mrs. Salinero’s actual medical history. It is quite another to opine that Mrs. Salinero will suffer “lifelong complications,” *see* Margolis Rep. at 47, without ever having treated or examined Mrs. Salinero. Though Dr. Margolis tacks on the phrase “[m]ore likely than not and within a reasonable degree of medical certainty,” *id.*, these are not

“magic words” that render reliable his projections about Mrs. Salinero’s medical future. *Cf. Williams v. Int’l Paper Co.*, No. 108-045, 2009 WL 10678735, at *5 (S.D. Ga. June 30, 2009) (though expert could testify “to a reasonable degree of medical certainty” that Cushing syndrome is a known consequence of taking corticosteroids, he could not testify that the plaintiff may, or will, develop Cushing syndrome as a result of his exposure). Dr. Margolis employs no methodology whatsoever in reaching this conclusion. Though he has experience in treating patients with polypropylene-containing pelvic mesh, his qualification is not the same as a reliable opinion about Mrs. Salinero’s future prognosis. “If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.” *Frazier*, 387 F.3d at 1261. Accordingly, the Motion is GRANTED on this ground; Dr. Margolis may not opine about Mrs. Salinero’s anticipated future medical complications.

B. Dr. Iakovlev

Dr. Iakovlev is an anatomical pathologist who seeks to opine that Prolene in Artisyn Mesh can degrade in the human body and otherwise pose serious health risks after implantation in the human body. *See generally* D.E. 156-10 (“Iakovlev Rep.”). Prolene is comprised of polypropylene and other additives. *See, e.g.*, D.E. 232-3 at 8–9. Defendants move to exclude Dr. Iakovlev’s general opinions regarding risks associated with Prolene mesh, including his opinion that polypropylene in Prolene degrades in the human body, and his case-specific opinions Mrs. Salinero’s injuries and prognosis are due to the presence of polypropylene in Artisyn Mesh.

As to the general opinions, Defendants argue: (1) Dr. Iakovlev’s degradation opinions and the underlying methodology are not generally accepted in the scientific community, have not been subject to valid testing, and are not supported by published scientific literature; (2) Dr. Iakovlev lacks specialized knowledge sufficient to testify about potential injuries to the female body; and (3) Dr. Iakovlev’s histological analysis is unreliable because he failed to use a control; (4) Dr. Iakovlev’s opinion that the presence of an erosion necessarily implies that the patient had a wound infection is unreliable; (5) Dr. Iakovlev’s mesh folding and deformation opinions are unreliable; and (6) Dr. Iakovlev should be precluded from offering opinions based on mesh not at issue in this case or mesh that he cannot identify.

*8 As to the case-specific opinions, Defendants argue: (1) Dr. Iakovlev’s case-specific opinions are based on the same unreliable methodology as his general opinions; (2) his vague testimony would not aid the trier of fact; (3) Dr. Iakovlev does not treat patients, has never met Mrs. Salinero, and did not review any depositions before offering his speculative case-specific opinions; and (4) his opinion about what happened to Mrs. Salinero’s mesh is unreliable speculation based on review of histology slides alone.

1. Qualifications

Plaintiffs argue that Dr. Iakovlev is qualified to render each of the objected-to opinions given his broad education, training, and experience. *See* D.E. 192 at 9–11. He has training and experience specifically related to mesh implants, and has written on, *inter alia*, the foreign body reaction to polypropylene mesh implanted in the body, the oxidation and degradation of polypropylene mesh, the implications of polypropylene degradation, and the complications associated with polypropylene mesh, including migration of the mesh, erosion of the mesh, infection, pain, and the causes of that pain. *See id.*; *see also* Iakovlev Rep. at 5–13 & Ex. A-1 thereto (curriculum vitae).

The Court agrees with the MDL Court that Dr. Iakovlev may testify to causation because, as an academic pathologist who has reviewed the literature and has experience assessing the reaction of the human body to polypropylene, he is qualified to explain and to analyze and examine human tissue to assist the jury in understanding how Mrs. Salinero’s body reacted to the Prolene mesh and the mechanisms of Mrs. Salinero’s injuries. *See, e.g., Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 712 (S.D. W. Va. 2014) (rejecting the argument that, as a pathologist and not a urogynecologist, Dr. Iakovlev is unqualified to render a clinical opinion); *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *24–25 (S.D. W. Va. July 8, 2014) (noting that, according to Ethicon’s own expert in the case, “pathologists can help diagnose clinical problems, including symptoms such as pain and bleeding,” and finding Dr. Iakovlev qualified to render specific causation opinions). Defendants have not shown why this Court should rule to the contrary. Accordingly, the Court finds Dr. Iakovlev qualified to render both his general and specific causation opinions in this case.

2. Reliability

a. General Causation

i. Dr. Iakovlev's own histological testing

Defendants object that Dr. Iakovlev's opinions are based on his own unreliable testing. Specifically, Defendants argue that Dr. Iakovlev's opinion that Prolene mesh can degrade in the human body and cause adverse clinical effects is based on a faulty foundational premise: that his own histological studies applying stains to explanted mesh specimens demonstrate a degraded outer layer visible under light microscopy.⁹ They argue that Dr. Iakovlev's histological analysis included meshes that do not contain polypropylene and are of unknown origin. They also argue that Dr. Iakovlev failed to use any control in his histological analysis.

First, Defendants point out that Dr. Iakovlev's Report cites to his review of "over 500 specimens of meshes explanted from the female pelvis, from the groin and the anterior abdominal wall." Iakovlev Rep. at 8. Further, Dr. Iakovlev has testified in other cases that many of the meshes in his data pool are not made of polypropylene and "[a]t least a half" were supplied to him for consultation in connection with litigation, with some meshes even being supplied by the plaintiffs' attorneys themselves. *See* D.E. 156-29 at 75:10-78:5, 79:18-21; D.E. 156-22 at 59:25-60:12; *compare also* D.E. 156-28 at 2 (in earlier case, noting that he has reviewed approximately 100 specimens of explanted meshes made of not only polypropylene but also of "GoreTex and combined designs") *with* D.E. 156-29 at 99:10-21 (testifying that the prior case's mesh samples were part of the "500 samples" on which he has relied to form opinions in his report). He has also testified that he has had "difficulty tracing all of" his samples "back" to their origins. D.E. 156-16 at 107:15-109:5; *see also id.* at 20:22-21:22.

⁹ To the extent Dr. Iakovlev's opinions are based on a data pool that includes meshes of types that are not at issue in this litigation (e.g., meshes that do not contain polypropylene) and were selectively supplied to him for litigation consulting purposes without his being able to identify the origins of the samples, the opinions are unreliable and will be excluded. *Cf. In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582228, at *5 ("Such indeterminacy raises concerns about the integrity of Dr. Iakovlev's data pool, as the selection

and origin of samples may necessarily affect the conclusions that may reliably be drawn from them.").

As to the claim that Dr. Iakovlev failed to use a control in his histological analysis, Plaintiffs argue that it would simply be impossible to have a "control": "Healthy people do not undergo surgery and have healthy tissue excised...." D.E. 192 at 17. However, that is what the scientific method—and *Daubert*—requires. *See, e.g., Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 537 (S.D. W. Va. 2014) ("Vigorous adherence to protocols and controls are the hallmarks of 'good science.' ") (quoting *Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *26-28 (S.D. W. Va. Sept. 29, 2014)). The MDL Court has so held: "Without a proper control, Dr. Iakovlev's opinions correlating specific complications with samples of explanted mesh products do not provide a sufficiently reliable methodology. To the extent that Dr. Iakovlev offers complications opinions based on his examination of explanted mesh samples without the use of a control sample, his complications opinions are **EXCLUDED.**" *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582228, at *4 (emphasis in original). This Court adopts that ruling as its own.

As the Court understands Dr. Iakovlev's Report, the effect of these rulings is that Dr. Iakovlev's general and specific causation opinions to the extent based on his histological study in which he applied stains to explanted mesh specimens will be EXCLUDED.

ii. Other sources for Dr. Iakovlev's degradation opinions

Defendants emphasize that Dr. Iakovlev has described the phenomenon of cracking on the outer layer of polypropylene mesh visible under light microscopy as "bark" around the fiber. *See* Mot. at 10. Defendants argue that the "bark theory" and its underlying methodology have not been generally accepted by the scientific community, have not been validated, and are not supported by published scientific literature. *Id.*

The Court has decided *supra* that Dr. Iakovlev may not opine to general causation based on his histological study. However, Plaintiffs respond that Defendants' "bark theory" argument is misleading because Dr. Iakovlev's general causation opinions—"bark" or otherwise—do not depend on his testing. Plaintiffs maintain that his degradation opinions are based on ample scientific literature and studies, including

those performed by Ethicon's own scientists, concluding that polypropylene pelvic mesh "oxidizes and degrades in the body; the outer surface becomes porous, which causes it to crack and become embrittled and leads to complications and the failure of the product." D.E. 192 at 14.

After careful review of the Report as well as depositions of Dr. Iakovlev in this and other proceedings, the Court finds that Dr. Iakovlev's opinions are not dependent on his histological study. In fact, several hundred pages of his report consist of an extensive literature review and review of Ethicon's own studies and internal documents. As far as the Court can ascertain, (1) these are central source documents that are the foundation for his general causation opinion regarding degradation, (2) these documents support his general causation opinion and (3) therefore, he need not rely on his histological study to state his general causation opinion at trial. For example, as Dr. Iakovlev testified in his *de bene esse* deposition regarding his degradation opinions:

*10 Q. And all of these opinions that you have just given us, is this based solely upon your res – based solely upon your research of the literature or does this also include your own independent research?

A. Both. Both in the published literature, my research, as well as internal documents. When I describe th[ese] findings in the manuscript and the manuscript was accepted, I was shown internal Ethico[n] documents where Ethicon scientist did exactly the sam[e] work using exactly the same methodology 30 years bef[ore] me.

Q. Did you know that at the time you were doing your study?

A. No, I wasn't. I thought that I'm the discoverer of this thing, and – or at least how it looks in the histological sections. I was [a] little bit disappointed that somebody preceded me by 30 years. It was not published, so I couldn't find it in the PubMed. But they did exactly the same, exactly the same sections. They examined in regular light and polarized light, an[d] their conclusion was that it degrades.

D.E. 232-3 at 18. Thus, though Dr. Iakovlev may have himself conducted some histological testing with unreliable conclusions (due to the questionable data pool and lack of a control), Dr. Iakovlev's experience in studying others' histological and other analyses renders his degradation opinions sufficiently reliable.

The Court further notes that the MDL Court has declined to exclude all of Dr. Iakovlev's general causation opinions simply because Dr. Iakovlev conducted his own histological testing that led him to conclude that degraded polypropylene looks like bark. Judge Goodwin stated: "Dr. Iakovlev's testimony on degradation generally is extensively supported with specific references to the scientific literature and several internal Ethicon documents. His manner of corroborating the scientific literature by performing his own tests to detect degradation is only one facet of his testimony. I will not order a blanket exclusion of Dr. Iakovlev's degradation testimony based on Ethicon's misleading representations." *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582228, at *3 (S.D. W. Va. Sept. 1, 2016). This Court agrees. Therefore, the Motion will be denied with respect to Dr. Iakovlev's general causation opinion that Prolene degrades.

iii. Clinical complications caused by degradation

Defendants complain that the scientific literature on which Dr. Iakovlev relies to state the degradation causes clinical complications is unreliable. They quote one of Dr. Iakovlev's own papers, which reports that "[p]olypropylene degradation may play a role in the continuous inflammatory response, mesh hardening and late deformations." Mot. at 14 (citing D.E. 156-11 at 512 (emphasis in Motion)). This conclusion, Defendants argue, does not allow Dr. Iakovlev to conclude that degradation actually results in clinical complications. Plaintiffs argue that Defendants misunderstand Dr. Iakovlev's opinions in this regard. In his Report, Dr. Iakovlev stated with respect to the degradation and erosion observed with mesh implants: "Although changes occur in all patients, the severity and cumulative effect is variable. As with other diseases, the manifestations range from subclinical to fully developed complications." Iakovlev Rep. at 105. Similarly, when asked about injuries that result from degradation, Dr. Iakovlev testified that "you cannot take one feature of a device and connect it with a specific clinical presentation. It would be wrong because everything happens at the same time in the same area." D.E. 192-20 ("Iakovlev Dep.") at 76:7-10. At this stage, the Court finds that Dr. Iakovlev may reliably opine that mesh implantation and consequent polypropylene degradation can "contribute to the mechanisms of complications." Iakovlev Rep. at 77, 105. Plaintiffs may challenge this opinion through cross-examination or by presenting contrary evidence.

iv. Erosion as proof of a wound infection

*11 Defendants next state: “Dr. Iakovlev seeks to opine that Prolene mesh causes erosions in patients, and that the existence of an erosion establishes the presence of a wound infection.” Mot. at 15 (citing Iakovlev Rep. at 61–62, 112). Specifically, Dr. Iakovlev’s report states that “mesh exposure through skin or mucosa causes a chronic wound[.]” Iakovlev Rep. at 111, and “a chronic wound of a mechanically disrupted skin or mucosa serve[s] as an entry for infection[.]” *id.* Defendants posit that Dr. Iakovlev’s report necessarily implies that where there is an erosion, there is also a wound infection. *See* Mot. at 15–16. Defendants therefore move to exclude such opinions as unreliable.

Plaintiffs do not specifically respond to this argument but argue generally that mesh erosion though the tissues contributes to clinical complications. *See* D.E. 192 at 16. This is what Dr. Iakovlev’s Report reflects: “Erosion of mesh through mucosal surfaces or skin exposes the tissues and the mesh to bacterial contamination. This can lead to subclinical or clinically apparent infection (discussed later).” Iakovlev Rep. at 61 (emphasis added). He also states that “mesh exposure through skin or mucosa causes a chronic wound with subsequent risks for infection, discharge, bleeding, and a potential for generalized sepsis.” *Id.* at 111 (emphasis added).

In this regard, Dr. Iakovlev’s Report and testimony in this case is distinguishable from that before the MDL Court. *In In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582228, at *5, Dr. Iakovlev testified in the earlier case that “erosion is always associated with localized infection,” and his report stated that “[m]ucosal erosion of the transvaginal Ethicon mesh becomes a chronic open wound and an entry for infectious organisms.” (alterations in original). These opinions, which apparently were applicable in any event to transvaginal mesh, were absolute: if erosion, then infection. Here, by contrast, Dr. Iakovlev talks in terms of “risk” and “exposure.” His opinions about clinical possibilities are permissible, to the extent supported by scientific literature rather than speculation. Nevertheless, to the extent Dr. Iakovlev intends to testify at trial that erosion-caused wounds will result in infection, as a matter of scientific certainty, the Court agrees with the MDL Court that such an opinion is unreliable. *See id.* at *5.

b. Case-Specific Opinionsi. Same methodology as general causation opinions

The Court has already ruled on the reliability of Dr. Iakovlev’s general causation opinions. To the extent Defendants argue that Dr. Iakovlev’s case-specific opinions are unreliable for the same reasons as his general causation opinions, the Court imports its general causation rulings to the case-specific opinions.

ii. Failure to reliably link Mrs. Salinero’s fistula to any degradation

Dr. Iakovlev testified that Mrs. Salinero’s “main problem” was the “ability of mesh [to] penetrate through the tissue” leading to “a fistula and erosion through the organs.” Iakovlev Dep. at 46:17–47:13. He testified that, to reach that conclusion, he examined histological slides of tissue taken from Mrs. Salinero during the revision surgery that showed degradation. *Id.* at 74:24–75:2.

Defendants argue that Dr. Iakovlev cannot reliably link the alleged degradation to his opinion on Mrs. Salinero’s “main problem” (i.e., the fistula) because he testified that even if he hadn’t “seen” evidence of degradation, he would still opine that the mesh caused the fistula. *See id.* at 76:17–79:9. The Court disagrees. As Dr. Iakovlev explained, his opinion that degrading mesh caused the fistula is based on his knowledge of what happens to polypropylene mesh that has been explanted years after having been implanted, and his knowledge of the various complex changes in the tissue occurring all at the same time as the mesh migration and erosion (such as inflammation and scarring), *see id.*; if he did not “see degradation for whatever reason, [his] opinion would be the same” and he “would have to investigate why [he didn’t] see a degradation,” such as if he was looking at a “nonrepresentative histology,” *id.* at 79:2–14. At this stage, the Court finds that Dr. Iakovlev’s testimony is sufficiently reliable and would assist the trier of fact. Plaintiffs may challenge Dr. Iakovlev’s conclusions through cross-examination and the presentation of contrary evidence.

iii. Risk of future complications

*12 Whereas Dr. Margolis impermissibly opined that “[m]ore likely than not and within a reasonable degree of medical certainty, Mrs. Salinero will suffer lifelong complications ...,” Margolis Rep. at 47 (emphasis added), Dr. Iakovlev takes a more measured approach. He opines that the Artisyn Mesh and the associated tissue changes caused Mrs. Salinero’s past harm, and as to the future, he opines only that “any residual parts of the mesh that were not removed during the excisions, as well as the tissue damage and scarring caused by the mesh and the subsequent surgeries continued and continue to pose a risk for pelvic complications for Mrs. Salinero, either related to damage of the bladder (urinary symptom/complications), the rectum (bowel symptoms/complications) or other pelvic tissues (general pelvic symptoms/complications such pain and dyspareunia).” Iakovlev Rep. at 271–72 (emphasis added).

The Court finds that Dr. Iakovlev may testify about the relevant possible complications that Mrs. Salinero may suffer in the future as a result of the alleged mesh degradation, so long as those possibilities are supported by his review of the scientific literature and the Ethicon studies and so long as he does not opine that Mrs. Salinero is (with any degree of certainty) going to develop such complications.

iv. Whether Mrs. Salinero’s mesh
folded or curved in her body

Defendants claim that Dr. Iakovlev cannot opine that Mrs. Salinero’s implanted mesh folded or curved because Dr. Iakovlev did not review the actual gross specimen. Plaintiffs counter that such review would not have been possible because the treating physician who removed the mesh, Dr. Sepulveda, discarded the explanted removed mesh instead of preserving it for analysis. D.E. 192 at 18.¹⁰ Nevertheless, Plaintiffs argue, Dr. Iakovlev did review a number of specimens that were taken and preserved, and his review of those specimens forms the basis of his opinions. *Id.* (citing Iakovlev Dep. at 162:6–164:17).

The Court agrees with Defendants that Dr. Iakovlev’s cannot infer from mere histology (slide analysis) that the mesh folded or curled in Mrs. Salinero. Dr. Iakovlev states in conclusory fashion that “[w]e just determine three-dimensional orientation by histology,” Iakovlev Dep. at 44:18–24, but does not describe any methodology that would explain his conclusion. *Cf. In re Ethicon Inc. Pelvic Repair*

Sys. Prod. Liab. Litig., 2016 WL 4582228, at *4 (“Ethicon disputes that Dr. Iakovlev can merely look at a pathology slide and infer that mesh curled or deformed in the body. In response, the plaintiffs do not address the reliability of Dr. Iakovlev’s method for determining whether mesh was folded *in vivo*. Accordingly, Dr. Iakovlev’s opinions on folding and curling are **EXCLUDED** to the extent they rely solely on his personal analysis of pathology slides, and Ethicon’s Motion is **GRANTED** on this point.”) (emphasis in original).

C. Dr. Dunn

Dr. Dunn is a professor in the department of Chemical and Biomolecular Engineering at Vanderbilt University. *See* D.E. 156-50 (“Dunn Rep.”) at 1. His background is in chemical engineering and as a polymer scientist. *See id.* at 1–3. Dr. Dunn seeks to testify that the polypropylene in Artisyn Mesh is susceptible to oxidative degradation and that Ethicon’s quality systems and risk management functions failed to duly account for the risks of oxidative degradation. Defendants move to exclude Dr. Dunn’s general causation opinions, arguing that he is both unqualified to offer such opinions and, even if he were, his opinions are unreliable and irrelevant.

1. *Qualifications*

a. Dr. Dunn is not qualified to opine about polypropylene
oxidative degradation in this case because such
degradation is only relevant insofar as the polypropylene
polymer can be found in implanted pelvic mesh

*13 Defendants first note that the MDL Court has repeatedly held that Dr. Dunn lacks the requisite qualifications to offer opinions regarding medical devices. Mot. at 29–30 & n.12 (collecting 24 cases in which Dr. Dunn’s testimony has been excluded). Dr. Dunn has never designed any type of medical device, nor have any of the polymers that he has designed been used in a medical device. D.E. 156-55 (“Dunn Dep.”) at 13:16–14:8. Nor has he worked as a consultant for a medical device company. *Id.* at 14:21-23. He has never taught any courses about medical devices or polypropylene, *id.* at 14:9-11, nor has he been hired by any manufacturer that incorporates polypropylene in its products, *id.* at 14:24–15:2. He admits that he is not an expert in biomaterials. *Id.* at 34:14-18. Though he participated in one study that he considers to be “consistent with part of a biocompatibility

testing,” he has never worked on the biocompatibility of polypropylene or Prolene. *Id.* at 34:19–35:1. He is not involved in clinical research regarding polypropylene or mesh. *Id.* at 35:2–4.

Plaintiffs counter that Dr. Dunn is well-qualified to opine on polymer product failures. *See* D.E. 192 at 25–26. They assert that Dr. Dunn has conducted his own *in vitro* (laboratory) testing to confirm the oxidative degradation of Prolene and has presented the results of such testing both in a written article (the “Talley Article”) and at national and international conferences. *Id.* at 26. And they argue that Dr. Dunn does in fact have some medical-device-related experience. His expert report notes that “he ha[s] taught and [is] currently teaching polymer product safety case studies, including medical device case studies ... at Vanderbilt University.” Dunn Rep. at 2. He also has been conducting analyses on polymer-based tracheotomy tubes and spinal inserts—but only in connection with pending litigation, having been hired by an attorney to conduct these analyses. Dunn Dep. at 13:5–15, 154:9–24. Finally, Plaintiffs argue that the MDL Court has, on at least two occasions, permitted Dr. Dunn to testify. *See* D.E. 192 at 27 (citing *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D. W. Va. 2014), and *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923 (S.D. W. Va. July 8, 2014)).

First, the Court notes that Dr. Dunn’s experience teaching medical device case studies is not equivalent to having conducted his own medical device analyses. Indeed, Dr. Dunn’s “Polymer Product Failure Analysis Expertise” recounts having experience analyzing polypropylene product failures for applications such as support harnesses in commercially available deer stand kits, child car seat components, automotive speaker grills, and plastic chairs. None of these are medical devices. Though Dr. Dunn states in conclusory fashion that his expertise “is relevant to all polymer products in any application, including medical products that are used as an implantable device like pelvic mesh,” the Court is not convinced. As the MDL Court has noted, “[e]ven if Dr. Dunn relies on general engineering principles that apply to polymer products across the board, the opinions set forth in his expert report are clearly outside the scope of basic engineering.” *See, e.g., Wilkerson v. Bos. Sci. Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *18 (S.D. W. Va. May 5, 2015). Dr. Dunn’s general polymer laboratory testing expertise is too far afield of what would be useful to the trier of fact here.

Next, the Court distinguishes Plaintiffs’ cited cases. As the MDL Court has noted, “Ethicon did not object to Dr. Dunn’s qualifications in *Huskey*,” as Defendants do here. *Mathison v. Bos. Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *21 (S.D. W. Va. May 6, 2015). So too with *Edwards*. *See* 2015 WL 3361923, at *27 (analyzing Dr. Dunn’s proposed opinions for reliability and helpfulness to the trier of fact, but not his qualifications). By contrast, where defendants have challenged Dr. Dunn’s qualifications to opine about medical devices, the MDL Court has routinely excluded those opinions. *See, e.g., Sederholm v. Bos. Sci. Corp.*, No. 2:13-cv-12510, 2016 WL 3282587, at *5 (S.D. W. Va. June 14, 2016) (“All of Dr. Dunn’s opinions are premised on his belief that the polypropylene mesh in BSC’s devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility and that he is not qualified to opine on the way polypropylene may affect the body physiologically. I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case, and his opinions are **EXCLUDED**.”) (emphasis in original); *see also* cases cited in Mot. at 29–30 n.12.

*14 Plaintiffs argue that the MDL Court’s prior exclusions were in cases where Dr. Dunn proposed to testify about the effects of polypropylene in the body, whereas he now proffers opinions only as to polypropylene oxidative degradation outside of the body. The Court agrees with Defendants that Dr. Dunn’s opinions are merely a “repurposed version of the opinions that the MDL Court excluded.” D.E. 196 at 12. Dr. Dunn’s (limited) experience testing Prolene oxidative degradation *in vitro* is only relevant insofar as Plaintiffs ask the jury to find that Prolene similarly degrades *in vivo*. This, he cannot do. This case turns on how the polypropylene in Defendants’ Artisyn Mesh product reacted in Mrs. Salinero’s body. And, Dr. Dunn repeatedly testified that he cannot opine on polypropylene oxidation within the body, other than to opine that polypropylene is generally susceptible to oxidation outside of the body. *See* Dunn Dep. at 35:5–38:14, 95:2–5, 114:20–23. Accordingly, the Court agrees with the MDL Court that Dr. Dunn is unqualified to opine about polypropylene as it relates to implanted medical devices. It follows that Dr. Dunn is unqualified to opine about polypropylene *in vitro* to the extent such testimony is intended to be the basis for a necessary inference that polypropylene—and specifically, the Prolene in Artisyn Mesh—reacts the same way *in vivo*.

b. Dr. Dunn is not qualified to opine about medical device risk management, Ethicon's quality systems, alleged failure to comply with regulations, or biocompatibility review

Even if Dr. Dunn were qualified to testify about polypropylene oxidative degradation in general, he certainly is not qualified to opine about medical device risk management or Ethicon's quality systems or review of biocompatibility. His complete lack of experience working for or consulting with medical device manufacturers is practically dispositive. Nor is he qualified to testify about the Defendants' failure to follow regulatory standards ("ISOs"). Even if Dr. Dunn himself followed ISOs when conducting his *in vitro* polypropylene oxidative degradation testing, this does not render him qualified to opine that Defendants' failed to follow the standards, as he is not a regulatory expert.

2. Other Daubert Prongs

Even if Dr. Dunn's *in vitro* opinions were permissible under *Daubert*'s qualification prong, the Court alternatively holds that those opinions are irrelevant and would not aid the trier of fact, as they would unnecessarily complicate the issues and potentially mislead the jurors into thinking the *in vitro* test results are necessarily the same as what would happen *in vivo*. Further, Dr. Dunn's opinions are irrelevant to the extent he disclaims any intent to opine on polypropylene oxidation in the body. *See* Dunn Dep. at 123:24–124:14 (disclaiming any intent to testify about whether Mrs. Salinero's mesh oxidized in her body "[b]ecause my expertise is polymer analysis and polymer properties. ... I'm trying not to cross the boundary of once this polymer material is implanted in the body, what the body does to the polymer. That's what Dr. Guelcher has expertise on."). The fact that Dr. Dunn has observed some non-Ethicon explanted polypropylene material with "oxidation on it," *see id.* at 110:23–25, does not permit him to reliably opine that Prolene in implanted Artisyn Mesh is likely to undergo oxidative degradation while in the body. *See also id.* at 76:7–10 (testifying that he has never tested explanted Prolene).

In sum, the Motion to exclude Dr. Dunn's opinions and testimony is GRANTED.

D. Dr. Guelcher

Dr. Guelcher is a co-author of the Talley Article, along with Dr. Dunn. *See* D.E. 156–32. Dr. Guelcher's proposes to extend Dr. Dunn's conclusions about polypropylene oxidative degradation *in vitro* to opine that the oxidative degradation also occurs *in vivo*. *See* D.E. 156–31 ("Guelcher Rep.") at 3. Specifically, Dr. Guelcher begins his Report by stating that polypropylene outside the body reacts with oxygen, resulting in chain scission and deterioration. *Id.* ¶ 1. Next, he opines that polypropylene mesh inside the body also reacts with oxygen and leads to, *inter alia*, degradation, embrittlement, flaking, pitting, and cracking, which reaction continues unless and until the implanted device is removed in its entirety. *Id.* ¶¶ 2–4.

1. Qualifications

a. Dr. Guelcher is unqualified to opine about clinical complications caused by degraded or degrading mesh

*15 Dr. Guelcher is currently a Professor of Chemical and Biomolecular Engineering at Vanderbilt University. Guelcher Rep. at 1, 113. Plaintiffs argue that Dr. Guelcher has extensive experience with implantable biomedical materials and has written extensively on biomaterials, including 94 published peer-reviewed articles. *See id.* at 113–147 (curriculum vitae). He has written papers on and reviewed other scientists' work related to complications due to the body's foreign body response to synthetic materials. *See id.* Dr. Guelcher specifically has written articles and presentation abstracts pertaining to polypropylene in biomedical devices. *See id.* at 2, 115, 119–120, 138–39.

Defendants argue that Dr. Guelcher is not qualified to opine that polypropylene degradation *in vivo* causes clinical complications in patients, such as pain and scarring. *See* Mot. at 26. Dr. Guelcher is not a medical doctor—he has never explanted or implanted mesh—nor has he clinically tested mesh *in vivo* to see whether and how it symptomatically manifests. *See* D.E. 156–38 ("Guelcher Dep.") at 12:19–24, 32:13–33:3. Plaintiffs claim that Dr. Guelcher's research and writing necessarily "requires a full understanding of the body's reaction to synthetic materials and the possible complications associated with introduction of these materials into the body and/or the bones and tissue in the body." D.E. 192 at 8. Plaintiffs cite two publications, D.E. 192–8 and D.E. 192–12, which Dr. Guelcher reviewed—but did not author—as support that he understands clinical complications stemming from foreign body reaction to polypropylene mesh.

The Court agrees with Defendants that Dr. Guelcher is not qualified to opine about clinical manifestations of the body's response to implanted polypropylene mesh for the same reasons articulated by the MDL Court:

Dr. Guelcher is not a medical doctor; instead, he is a chemical engineer. Dr. Guelcher has not examined patients, and he has not conducted [differential diagnoses](#). Dr. Guelcher is simply not qualified to offer opinions on medical complications that may be caused by polymer degradation. Accordingly, Dr. Guelcher's opinions regarding complications resulting from alleged polypropylene degradation are **EXCLUDED**.

In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4547055, at *3 (S.D. W. Va. Aug. 31, 2016) (emphasis in original). The Motion therefore will be GRANTED on this ground.

2. Reliability

The remainder of Defendants' challenges to Dr. Guelcher's opinions speak to the *Daubert* reliability prong.

a. Dr. Guelcher's opinions are unreliable to the extent they rely on the Talley study

Of Defendants' many challenges to Dr. Guelcher's opinions, the most persuasive is the unreliability of the opinions as based on the Talley study.

First, the Court notes that the MDL Court, at least as recently as August 10, 2018, has routinely excluded Dr. Guelcher's opinions to the extent that they are based on Dr. Dunn's testing, as Dr. Dunn's testing is unreliable. *See Armstrong v. Bos. Sci. Corp.*, No. 2:13-cv-24784, 2018 WL 3824375, at *5 (S.D. W. Va. Aug. 10, 2018). The MDL Court has also implicitly criticized the impermissible leap between Dr. Dunn's opinions, which by his own admission are not opinions about polypropylene's behavior *in vivo*,

and Dr. Guelcher's proffered opinions "on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant." *See id.* (excluding Dr. Guelcher's opinions because Dr. Dunn's testing is unreliable, but also noting that Dr. Dunn "stated in his deposition that he would only use his testing to show the general behavior of polypropylene mesh in an *in vitro* oxidizing medium—not to extend what that means inside the body"). As the Court stated above, to the extent Dr. Guelcher's opinions are founded on Dr. Dunn's predicate *in vitro* assessments (which includes the Talley Article that Dr. Dunn co-authored), they are due to be excluded.

*16 Moreover, Defendants present many arguments as to why the Talley study does not have sufficient indicia of reliability, including that (1) the authors purported to "recapitulate" *in vivo* conditions by using an oxidative medium composed of, *inter alia*, 20% hydrogen peroxide (the "Talley Medium"), and cited to one particular study (the "Zhao study") to support the composition of the Talley Medium, *see* Talley at 3 & n.17, but the Zhao study used an oxidative medium with only 10% hydrogen peroxide, *see* D.E. 156-37—the discrepancy between the Talley Medium and the Zhao study's medium was never explained; and (2) the Talley testing examined both untreated fibers and fibers that had been "scraped" in efforts to remove an outer layer of tissues and proteins, yet did not identify any protocol for "scraping," much less adhere to any protocol, *see* Mot. at 22–23 (citing, *inter alia*, *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 537 (S.D. W. Va. 2014) ("Vigorous adherence to protocols and controls are the hallmarks of 'good science.'")). Defendants do not respond to these challenges other than to say that the Talley Article "is a peer-reviewed reliable study" with findings that "were validated by the Defendants' own expert." D.E. 192 at 2. It is the proponent of the expert who bears the burden of showing reliability, *see Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999), and Plaintiffs simply have not carried that burden vis-à-vis the Talley study.

Plaintiffs argue that Defendants overstate Dr. Guelcher's reliance on the Talley study, and in any event, the scientific literature beyond the Talley article on which Dr. Guelcher relies supports his opinion that Prolene oxidizes and degrades in the body. That opinion, Plaintiffs claim, is also supported by Ethicon's own testing. Defendants appear to concede that Dr. Guelcher's opinions on polypropylene oxidative degradation may be admissible so long as those opinions do not depend on the Talley study: "Even if Dr. Guelcher's

reliance on other sources renders his general opinions admissible, the Court should, at the very least, preclude Dr. Guelcher from offering any opinions based on the Talley article or relying on the Talley article or relying on the article at trial.” D.E. 196 at 9. The Court so holds.¹¹ Dr. Guelcher may opine on polypropylene oxidation and degradation in the body, but only to the extent those opinions are based on his review of the scientific literature beyond the Talley study, and to the extent such literature discusses reliable testing of explants (or other reliable evidence of what occurs *in vivo*, rather than *in vitro*). See D.E. 196 at 10 (explaining why the Kurtz *in vitro* testing likewise cannot be extended to opine that oxidative degradation occurs *in vivo*).

b. The particular make-up of Prolene does not render unreliable Dr. Guelcher’s opinions based on other polypropylene

The Court does, however, reject Defendants’ contention that Dr. Guelcher’s recognition that Prolene is different from other polypropylene due to its additives (which retard degradation in polypropylene) is “fatal.” See Mot. at 19; see also D.E. 196 at 9 (arguing that the non-Talley-literature and Ethicon studies are still unreliable because “[n]early every article Dr. Guelcher cites involved a polypropylene mesh made by a different manufacturer rather than Prolene mesh made with its particular set of additives and antioxidants” and “[t]he few articles that actually address Prolene do not support the proposition that Prolene is subject to oxidation or degradation in the human body”). As with Dr. Margolis’s testimony, *supra*, these disputes would be the proper subject of cross-examination, not exclusion. The MDL Court has likewise rejected this argument. See *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D. W. Va. 2014) (“It is clear that the experts in this case do not consider Prolene to be different from polypropylene for the purposes of their opinions in this case. Therefore, to the extent that Ethicon contends that an expert’s opinions are unreliable or unhelpful because they do not account for the ‘important chemical differences’ between polypropylene and Prolene, this argument is rejected.”); see also *id.* at 709–10 (denying motion to exclude Dr. Guelcher’s opinions). Thus, to the extent Dr. Guelcher’s opinions rely on permissible sources, the fact that those sources involve non-Prolene mesh is immaterial.

3. Alternative Design Opinions

*17 Defendants also argue that Dr. Guelcher’s “safer alternative design” opinions should be excluded as unreliable. In his Report, Dr. Guelcher opines that “[u]sing autologous fascia lata, [allograft](#), or polyvinylidene fluoride (PVDF) mesh does not present with the same chronic complications associated with the material properties of Ethicon’s PP mesh.” Guelcher Rep. at 3 ¶ 8; see also *id.* at 23–26. Autologous fascia lata and [allografts](#) are two categories of biologic grafts, or surgical procedures using natural tissue. *Id.* at 23–24. PVDF is a synthetic polymer. *Id.* at 24. Dr. Guelcher relies on other researchers’ studies of the *in vivo* comparison between Prolene and PVDF, as well as Ethicon’s own testing and funded studies, to conclude that PVDF meshes are less likely than Prolene meshes to degrade, crack, and cause lower inflammation and fibrosis in the human body. See *id.* at 24–26.

At the outset, as the Court has already noted, Dr. Guelcher is not a clinician. He is not qualified to opine on clinical complications flowing from polypropylene mesh degradation *in vivo*. It follows that Dr. Guelcher’s opinions that an alternative design is less likely to cause complications are also unreliable.

Moreover, the MDL Court has held that [surgical procedures](#) such as biologic grafts are not actually “alternative designs” to synthetic pelvic mesh products. *E.g.*, [Mullins v. Johnson & Johnson](#), 236 F. Supp. 3d 940, 942–44 (S.D. W. Va. 2017). This Court agrees. Accordingly, Dr. Guelcher’s opinions that autologous fascia lata and [allografts](#) are “safer alternative designs” are EXCLUDED.

As to PVDF mesh, Plaintiffs argue that these opinions are based on reliable studies, including those by Ethicon itself, concluding that such mesh performs better than the Defendants’ polypropylene-based products. Defendants argue that the studies do not irrefutably establish that any synthetic alternative mesh materials are safer or as effective as Artisyn Mesh. The Court concludes that Dr. Guelcher’s opinions about PVDF meshes and their relative likelihood to degrade are the kind of “shaky but admissible” evidence that is not barred by *Daubert* and is the proper subject of cross-examination. See [Allison v. McGhan Med. Corp.](#), 184 F.3d 1300, 1311 (11th Cir. 1999). Accordingly, the Motion is DENIED as to the PVDF mesh opinions. The Court reiterates that the opinions must be limited to polymer degradation, erosion, cracking, or other effects which are within the realm of Dr. Guelcher’s expertise; he may not opine about the body’s symptomatic responses to the polymer reactions.

**E. Testimony as to Purported Knowledge,
State of Mind, and Alleged Bad Acts**

Defendants argue that each of Plaintiffs' experts inappropriately intends to testify regarding Defendants' purported knowledge, state of mind and alleged bad acts. The Court agrees with Defendants, and with the MDL Court, that a corporate defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); accord, e.g., *In re Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *3–4 (S.D. W. Va. Aug. 30, 2016) (precluding state-of-mind/intent and legal-conclusion expert testimony, as it would effectively usurp the jury's fact-finding function); *Wilkerson v. Bos. Sci. Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *3 (S.D. W. Va. May 5, 2015) (same); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 517–18 (S.D. W. Va. 2014) (same); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-02327, 2014 WL 186872, at *15 (S.D. W. Va. Jan. 15, 2014) (same).

The same is true of Dr. Margolis's purported testimony about the knowledge and state of mind of average physicians in the medical community; the Court has already ruled that Dr. Margolis is unqualified to offer such opinions and, in any event, the opinions would be unreliable as based solely on his own *ipse dixit*.

*18 Finally, the Court also agrees with Defendants that Dr. Margolis may not simply summarize or interpret documents or other witnesses' testimony. "[A]n expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions," *C.R. Bard*, 948 F. Supp. 2d at 611, but simply parroting documents or other testimony does nothing to assist the trier of fact. See *United States v. Frazier*, 387 F.3d 1244, 1262–63 (11th Cir. 2004) ("Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments.").

Accordingly, the Motion is GRANTED on these grounds.

**F. Testimony Regarding Complications or Risks
that Mrs. Salinero Does Not Claim to Have Suffered**

Defendants argue that the Court should preclude Plaintiffs' experts from testifying about risks or complications that Mrs. Salinero does not claim to have suffered, such as [cancer](#). Mot. at 40. Plaintiffs do not address this argument in their response. The Motion is therefore due to be granted on this ground by default; moreover, Defendants' argument is obviously meritorious. See, e.g., *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 553 (S.D. W. Va. 2014) (where no plaintiffs claimed that product caused [cancer](#), expert's opinions on the carcinogenicity of polypropylene would "offend Rule 702 and confuse the jury on a matter with scant probative value"). The Motion is also GRANTED on this ground.

IV. CONCLUSION

For the reasons discussed *supra*, it is

ORDERED AND ADJUDGED that that Defendants' Motion, D.E. 156, is GRANTED IN PART AND DENIED IN PART as follows:

1. **Dr. Margolis's** opinions are EXCLUDED to the extent they relate to: (1) the FDA (absent prior leave of Court, see *supra* n.2), (2) IFU warnings, (3) Defendants' testing of Artisyn Mesh, (4) medical professionals' reliance on warnings and/or marketing, (5) any other testing- or marketing-related issues, (6) Artisyn Mesh's alleged small pore size and heavy weight, and (7) Mrs. Salinero's future prognosis. In all other respects, the Motion is DENIED.
2. **Dr. Iakovlev's** opinions are EXCLUDED to the extent they: (1) suggest that erosion of mesh will necessarily lead to [wound](#) infection; (2) are based on examination of explanted mesh samples without the use of a control sample; (3) are based on non-polypropylene meshes and/or mesh samples whose origins he cannot identify; (4) suggest that Mrs. Salinero is (with any degree of certainty) going to develop certain future complications; and (5) state that Mrs. Salinero's mesh folded or curved *in vivo*, to the extent based only on review of slides. In all other respects, the Motion is DENIED.
3. **Dr. Dunn's** opinions are EXCLUDED in their entirety.

4. **Dr. Guelcher's** opinions are EXCLUDED to the extent they: (1) speak to clinical complications from degraded mesh, such as pain and scarring; (2) are based on the Talley study or otherwise rely on Dr. Dunn's excluded opinions; (3) offer surgical procedures as "alternative design" options; and (4) speak to the body's symptomatic responses to non-polypropylene synthetic alternative designs (i.e., PVDF meshes). In all other respects, the Motion is DENIED.

5. **None of the experts** may opine about Defendants' or others' purported knowledge, state of mind, or alleged bad acts.

6. **None of the experts** may opine about complications or risks that Mrs. Salinero does not claim to have suffered.

DONE AND ORDERED in Chambers at Miami, Florida, this 5th day of September, 2019.

All Citations

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Footnotes

- 1 Rule 104(a) provides: "The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible. In so deciding, the court is not bound by evidence rules, except those on privilege." This text is not the same exact text quoted in *Daubert* because Rule 104 was changed in 2011 as part of the Evidence Rules' restyling. This change was stylistic only and not intended to change "any result in any ruling on evidence admissibility." [Fed. R. Evid. 104](#) advisory committee's note to 2011 amendments.
- 2 Defendants also argue that Dr. Margolis is unqualified to opine about the Food and Drug Administration ("FDA") as he is not a regulatory expert and has not reviewed any FDA documents for Artisyn Mesh. However, Plaintiffs disclaim any intent to elicit testimony on this subject "unless the Defendants open the door to this testimony." D.E. 192. The Court therefore GRANTS the motion to exclude any FDA-related testimony by Dr. Margolis, but this ruling is subject to reconsideration at trial if Defendants "open the door." Plaintiffs shall not elicit any FDA-related testimony from Dr. Margolis without prior leave of Court.
- 3 *Cf., e.g., Maiz*, 253 F.3d at 665 (in civil RICO claim involving fraudulent real estate transactions, expert witness with "a Ph.D. in economics, extensive experience as a professional economist, and a substantial background in estimating damages" was qualified to assess the loss suffered by the plaintiff, even though he had no real estate development experience); *Buccellati Holding Italia SPA v. Laura Buccellati LLC*, No. 13-21297-CIV-MOORE/TORRES, 2014 WL 11901585, at *2–4 (S.D. Fla. Apr. 14, 2014) (expert with experience in overall marketing of consumer goods, generally, qualified to testify in trademark case about consumer confusion even though he had not specialized in the jewelry or handbag trade).
- 4 See also *Feliciano v. City of Miami Beach*, 844 F. Supp. 2d 1258, 1262-63 (S.D. Fla. 2012) (police practices expert qualified to testify in excessive force trial even though he had never heard of the common "knock and talk" investigative technique; expert's experience in law enforcement generally qualified him to render opinions concerning police practices, and lack of knowledge concerning the specific technique could be addressed through "[e]ffective cross-examination").
- 5 Further, Defendants' fifth argument on Dr. Margolis's general causation opinions—that Dr. Margolis lacks any information relating to Ethicon's Artisyn Mesh testing and therefore cannot opine on the same—is also sustained under the third *Daubert* prong. Dr. Margolis's testimony on Artisyn Mesh testing would not assist the trier of fact. Plaintiffs concede that, in his deposition testimony about testing, Dr. Margolis "simply took the Defendants at their word and quoted directly from the 2012 IFU accompanying" the Artisyn Mesh. D.E. 192 at 23. A fact finder is equally capable of reading the 2012 IFU text. Dr. Margolis's reading would impermissibly elevate the 2012 IFU's purely factual statement to a level of paramount "expert" importance. *Cf. Rosenfeld v.*

Oceania Cruises, Inc., 682 F.3d 1320, 1340 (11th Cir. 2012) (Tjoflat, J., dissenting from denial of rehearing en banc) (“[W]hen jurors need no assistance to understand the fact at issue, the expert’s testimony may lend undue credence to one party’s view of the facts because that testimony bears the imprimatur of an expert.”).

See D.E. 156-1 (Margolis Dep.) at 66:3–14.

This identification renders distinguishable Defendants’ cited case of *Keys v. Shell Oil Co.*, No. 6:14-cv-1161-Orl-37DAB, 2015 WL 12852307 (M.D. Fla. Apr. 24, 2015). There, the plaintiff claimed she was exposed to toluene, a clear liquid found naturally in crude oil, and as a result of this exposure, she developed *rectal cancer*. *Id.* at *1. Moving to dismiss the complaint, the defendant argued that the plaintiff had not identified a specific defect as to toluene. See *id.* at *2. The court agreed, finding the allegation that toluene is “potentially” carcinogenic to be merely consistent with liability, rather than plausibly stating a defect claim. See *id.* at *2–3. Here, Dr. Margolis has identified that the Artisyn Mesh contains polypropylene, and polypropylene allegedly causes the mesh to be defective/unsafe for permanent implantation because of its tendency to erode, degrade, and so on. This is a sufficiently specific defect identification.

Plaintiffs point out that Dr. Sepulveda, Mrs. Salinero’s treating physician, testified that when he removed Mrs. Salinero’s Artisyn Mesh, he did not see any evidence that it had degraded, fallen apart, contracted, shrunk, or retracted after he implanted it. D.E. 156-9 (“Sepulveda Dep.”) at 96:21–97:4. This testimony is not necessarily inconsistent with Dr. Margolis’s claimed findings of erosion and degradation: just because Dr. Sepulveda did not “see” this evidence at the time of explant surgery does not necessarily mean that the mesh had not actually eroded or degraded.

“Histology is the microscopic study of tissues through staining and sectioning and examining them under a microscope. Stains are used to highlight important features of the tissue.” Mot. at 10 n.5.

Insofar as this is a purported spoliation claim, see D.E. 192 at 18, the Court rejects it for, among others, the reasons set forth in Defendants’ reply, D.E. 196 at 8.

Because Dr. Guelcher’s opinions are due to be excluded to the extent they rely on the Talley study, the Court need not and does not address Defendants’ remaining reliability challenges to the Talley study, such as that the Talley test results were likely the result of contamination. Further, the Court notes that, even if it would permit Dr. Dunn to offer an opinion as to *in vitro* oxidative degradation of polypropylene in this case, he would also be precluded from relying on the Talley study for the reasons set forth herein.